

Remarks

Claims 1-35 were pending in the subject application. By this Amendment, the applicant has amended claims 1 and 31 and has canceled claim 2. No new matter has been added by these amendments. Support for the amendments to the claims can be found throughout the subject application including, for example, at page 4, lines 10-15 and page 8, lines 8-12. Accordingly, claims 1 and 3-35 are now before the Examiner for consideration.

The amendments set forth herein should not be interpreted to indicate that the applicant has agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. Favorable consideration of the claims now presented, in view of the remarks and amendment set forth herein, is earnestly solicited.

Claims 1, 2, 11, 20, 24, 25, 28-31, 34 and 35 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,758,836 (Zawacki). The applicant respectfully traverses the basis for this rejection because that Zawacki fails to teach or suggest all of the elements of the claimed invention.

The present invention provides a unique catheter for use during dialysis. As recited in the claims, a catheter is provided that functions primarily in "reverse-flow," having a dual lumen configuration in which the arterial lumen is disposed within the entire length of the venous lumen in a co-axial configuration and the arterial lumen extends beyond the termination point of the venous lumen. According to the subject invention, the arterial lumen is utilized to remove blood from the patient's vasculature while the venous lumen is utilized to return treated blood to the patient. By ensuring the arterial lumen is disposed within the entire length of the venous lumen in a co-axial configuration, fluid flow from the venous line completely encircles/bathes the segment of the arterial lumen that extends beyond the distal, terminal point of the venous lumen. High flow/high pressure return of blood at the distal, terminal point of the venous lumen over the arterial lumen ensures prevention or reduction of fibrin sheath formation around the arterial lumen. Prevention or reduction in fibrin sheath formation allows for improved catheter flow rates for longer periods of time than those generally observed with conventional catheters.

As titled, the Zawacki patent teaches a split tip dialysis catheter, where the catheter consists of at least two tubes that are arranged so that they “split” from each other along a distal portion of the catheter. The split tip or bifurcation of tubes is accomplished via a port that is provided along one tube, through which a second tube exits (see, for example, claims 1-46, col. 1, line 61 through col. 2, line 2; col. 3, lines 43-46, and title of the invention). Each tube has an open end at the tip (see, for example, col. 3, lines 47-49) that is separate from the port. Nowhere does Zawacki teach or suggest a catheter without a split tip or a catheter in which the tubes are arranged in a co-axial fashion throughout the length of at least one tube.

Further, Zawacki fails to teach or suggest use of the claimed catheter, rather, Zawacki merely teaches the placement of split tip catheters. All of the claims and examples disclosed by Zawacki lack language regarding a dual-lumen catheter in which an arterial lumen is disposed within the entire length of a venous lumen in co-axial configuration. In no instance does Zawacki indicate how a non-split tip catheter might be positioned such that the arterial lumen is situated in the right atrium of a patient’s heart and the venous lumen is situated in the superior vena cava. Thus, it is quite clear that Zawacki does not teach or suggest the currently claimed catheter and its use.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Cornell v. Sears Roebuck and Co.*, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman v. Kimberly-Clarke*, 218 USPQ 781 (Fed. Cir. 1983) (emphasis added). 221 USPQ at 485.

In *Dewey v. Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more

than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 52 USPQ 138 (2nd Cir. 1942).

As noted above, the Zawacki reference does not disclose or suggest a dual-lumen catheter in which the arterial lumen is disposed within the entire length of the venous lumen in a co-axial configuration. Nor does Zawacki teach or suggest placing such a catheter in a patient, wherein the arterial lumen is situated in the right atrium of a patient's heart and the venous lumen is situated in the superior vena cava. Unlike the claimed catheter, the Zawacki's catheter does not adequately prevent or reduce fibrin sheath formation because of the port and resultant split tip configuration of the catheter. Thus, under the applicable statutory and case law, the Zawacki reference does not anticipate the applicant's claims. Therefore, reconsideration and withdrawal of the rejection under 35 USC §102(e) is respectfully requested.

Next, applicant respectfully traverses the §103 rejections of claims set forth at pages 5-8 of the office action. Each of these rejections is based on Zawacki (U.S. Patent No. 6,758,836) as the primary reference. The deficiencies in Zawacki's catheter have been noted above and are respectfully reasserted herein. As such, the applicant respectfully notes that the teachings of the Zawacki reference do not serve to provide proper basis for the rejection of the claims as currently presented.

With regard to the rejection of claims 3-5, 12-14, 21-23, 32 and 33, the applicant respectfully submits that the Zawacki catheter is entirely different from what is currently claimed. Specifically, the Zawacki catheter has a split tip that is presented via a port in one tube through which another tube exits. Zawacki teaches that the port is necessary to enable desired positioning of the various tubes (see, for example, col. 4, lines 12-17). With such an arrangement, it is impossible for the tubes to have a co-axial configuration along the entire length of at least one tube. To modify the Zawacki catheter to make the applicant's claimed catheter would destroy the intent of Zawacki's invention, that being a split tip catheter.

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. The applicant submits that a fair reading of the Zawacki reference as a whole reveals that only split tip catheters are disclosed. To modify the Zawacki catheter to include

the claimed limitation (arterial lumen disposed within the entire length of the venous lumen in a co-axial configuration) would render the Zawacki catheter into a non-split tip catheter, which would be inoperable as intended. As such, a *prima facie* case of obviousness cannot properly be made.

Further, the applicant submits that it is only his own disclosure that teaches a dual lumen catheter having an arterial lumen disposed within the entire length of a venous lumen in a co-axial configuration, and the applicant's disclosure cannot be used to reconstruct the prior art for a rejection under 35 U.S.C. §103. This was specifically recognized by the CCPA in *In re Spomobile*, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 112 USPQ 364 (1959); *In re Sprock*, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield applicant's invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, “[b]oth the suggestion and the expectation of success must be founded in the prior art” *In re Dow Chemical Co.*, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). In the Zawacki reference, one finds neither. The applicant respectfully submits that any suggestion to modify the Zawacki catheter into a non-split tip catheter could only be arrived at through hindsight reconstruction, which is improper. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Regarding the rejection of claims 6, 7, 15, 16 and 26, Davey *et al.* (U.S. Patent No. 6,595,966) is cited as the secondary reference. The deficiencies of Zawacki are reasserted here. While Davey *et al.* describes tapering a catheter at a distal portion, Davey *et al.* fails to teach a dual-lumen dialysis catheter in which the arterial lumen, which extends beyond the distal point of the venous lumen, is disposed within the entire length of the venous lumen in a co-axial fashion. Further, neither reference teaches use of a dual-lumen catheter as claimed, wherein the arterial lumen

is placed in a right atrium and venous lumen is placed in a superior vena cava. Thus, the deficiencies of Zawacki are not cured.

With regard to the rejection of claims 9, 10, 18 and 19, Klein (U.S. Patent No. 5,762,631) is cited as the secondary reference. The deficiencies of Zawacki have been noted above, and are reasserted here. The applicant respectfully disagrees with the assertion in the Office action that a ridge and spoke are substantially similar; ridges run along a length of a lumen whereas a spoke is located on a specific spot on a lumen. Further, the applicant notes that Klein describes catheters having irregular surfaces in order to easily introduce one catheter within the other. It teaches nothing about the claimed catheter, whose arterial lumen is disposed within the entire length of venous lumen in a co-axial configuration and where the distal end of the arterial lumen extends beyond the distal end of the venous lumen. This fails to cure any of the shortcomings of Zawacki.

Finally, the rejection of claims 8 and 17 is based on Zawacki in view of Miller *et al.* (U.S. Patent No. 5,683,640). The deficiencies of Zawacki are reasserted here. While Miller *et al.* describes dual lumen catheters with both lumens concluding at the same point (*i.e.* are of same length), neither Zawacki nor Miller *et al.* teaches a dual-lumen catheter in which the arterial lumen, which extends beyond the distal point of the venous lumen, is disposed within the entire length of the venous lumen in a co-axial fashion, and thus the deficiencies of Zawacki are not cured

Because the deficiencies of the Zawacki reference have not been cured by any of the secondary references relied on in the office action, the obviousness rejections set forth at pages 5-8 should be withdrawn. Further, the applicant respectfully submits that any suggestion to a dual lumen catheter having an arterial lumen disposed within the entire length of a venous lumen in a co-axial configuration could only be arrived at through hindsight reconstruction, which is improper. Accordingly, reconsideration of the obviousness rejections set forth at pages 5-8 is respectfully requested.

In view of the foregoing remarks and the amendments above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Margaret Efron
Patent Attorney
Registration No. 47,545
Phone: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

MHE/la